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**From:** Charles Boyd[/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=30586A8D51E34852A9CD931EE5ECEB7C-CHARLES BOYD]  
**Sent:** Wed 3/24/2021 11:37:01 AM (UTC)  
**To:** Pat Boyd[PatB@Safechain.com]; Anthony Berger[Tonyb@Safechain.com]; Adam Brosius (Contact)[adam@pharmasales.com]  
**Subject:** FW: Gilead Sciences  
**Attachment:** Safe Chain Demand letter 3-23-2021.pdf

Morning guys,

I thought I'd wait until the morning to send this to save you some sleep. Take a look at the attached and let's discuss this AM.

CB



**Charlie Boyd** | Founder & CEO  
Safe Chain Solutions, LLC  
822 Chesapeake Drive | Cambridge, MD 21613  
office: 855.437.5727 | Cell: 301.875.1581  
[www.SafeChain.com](http://www.SafeChain.com) | [LinkedIn](#)

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**From:** Martha M. Rumore <mrumore@frierlevitt.com>  
**Sent:** Tuesday, March 23, 2021 9:34 PM  
**To:** Charles Boyd <CharlesB@Safechain.com>; Abbie Divilio <AbbieD@Safechain.com>  
**Subject:** FW: Gilead Sciences

Hi Charlie:

We received a demand letter from Gilead's Counsel. I will set up a meeting for us for tomorrow to discuss.

Best,

Martha

Martha M. Rumore, PharmD, MS, JD, LLM  
*Senior Counsel*

**FRIER LEVITT**  
ATTORNEYS AT LAW

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GOVERNMENT  
EXHIBIT

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DOJ-PPM-0000120004

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**From:** Beckerlegge, Robertson D. <[rbeckerlegge@bakerlaw.com](mailto:rbeckerlegge@bakerlaw.com)>  
**Sent:** Tuesday, March 23, 2021 6:15 PM  
**To:** Martha M. Rumore <[mrumore@frierlevitt.com](mailto:mrumore@frierlevitt.com)>  
**Cc:** McDonald, Heather J. <[hmcdonald@bakerlaw.com](mailto:hmcdonald@bakerlaw.com)>; Wallace, Kevin M. <[kwallace@bakerlaw.com](mailto:kwallace@bakerlaw.com)>  
**Subject:** Gilead Sciences

[EXTERNAL SENDER: This message came from an EXTERNAL address. DO NOT click on links or attachments unless you know the sender and the content is safe.]

Dear Ms. Rumore:

We have been retained by Gilead Sciences to address the issues related to the sale of counterfeit Gilead-branded medicines.

To that end, please see the attached letter.

If you have any questions or if would like to discuss, please let me know.

Thanks.

Robb Beckerlegge

**Robb Beckerlegge**

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**BakerHostetler**

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March 23, 2021

**VIA EMAIL (MRUMORE@FRIERLEVITT.COM) AND FEDERAL EXPRESS**

Martha M. Rumore, Pharm.D., Esq.  
Frier Levitt  
101 Greenwich Street, Suite 1203  
New York, NY 10006

**Re: *Re: Safe Chain's Continued Distribution of Counterfeit Gilead Medicine***

Dear Ms. Rumore:

This firm has been retained by Gilead Sciences, Inc. ("Gilead") to help protect its intellectual property and enforce its intellectual property rights. We write to follow up on Gilead's repeated attempts to obtain vital distribution chain information and also to inform Safe Chain Solutions, LLC ("Safe Chain") of two additional patient complaints in which Safe Chain has been identified as the source of counterfeit Gilead-branded medicines. This brings to five the total number of reported incidents involving patient complaints in which Safe Chain has trafficked in counterfeit medicines bearing Gilead-owned trademarks. Details of these incidents, along with three verification requests (one from Safe Chain itself) involving Safe Chain and falsified pedigree documentation, are referenced in the attached Appendix.

Safe Chain's failure to cooperate with Gilead to date over the previously reported counterfeit incidents and falsified pedigree documentation *and* Safe Chain's continued distribution of counterfeit Gilead-branded medicines shows a total disregard for patient safety. We therefore demand that Safe Chain immediately (1) quarantine all bottles of Gilead-branded medicine in its possession or control and provide Gilead with an opportunity to inspect them; and (2) provide documentation substantiating all purchases and sales of Gilead-branded medicine Safe Chain has made from January 2020 to the present, including the obligatory Drug Supply Chain Security Act (DSCSA) Tracing Documentation (pedigree documentation) that accompanied each

Atlanta Chicago Cincinnati Cleveland Columbus Costa Mesa Dallas Denver Houston  
Los Angeles New York Orlando Philadelphia San Francisco Seattle Washington, DC Wilmington

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transaction. We also demand that Safe Chain cease transacting in Gilead-branded medicine until our investigation into this matter is complete.

There is concrete and mounting evidence demonstrating that Safe Chain has trafficked in counterfeit Gilead-branded medicines and may be falsifying associated documentation. We remind you that under federal law (*see* 15 U.S.C. § 1117), Safe Chain's sales of counterfeit versions of Gilead medicines entitles Gilead to recover Safe Chain's profits resulting from the sale of counterfeit versions of Gilead-branded medicines, statutory damages, compensatory damages, treble damages, and costs and attorneys' fees. In addition, the Federal Food, Drug, and Cosmetic Act establishes both civil and criminal penalties for sales of adulterated, misbranded, and counterfeit drugs. *See, e.g.*, 21 U.S.C. § 331. Congress has specifically imposed criminal penalties on any person who "intentionally . . . traffics in a drug and knowingly uses a counterfeit mark on or in connection with such drug." *See* 18 U.S.C. § 182320(a)(4).

Gilead requires a response from Safe Chain to its requests within three business days to include the following:

- (1) confirmation that Safe Chain has quarantined all Gilead-branded medicine in its possession or control and ceased the purchase and sale of Gilead-branded medicine;
- (2) documentation, including pedigree documentation, substantiating purchases and sales of all Gilead-branded medicines identified in the Appendix;
- (3) assurances that going forward Safe Chain will fully cooperate with Gilead in investigating Safe Chain's sale of counterfeit Gilead-branded medicines; and
- (4) within seven (7) days, provision to Gilead of the requested documentation concerning the purchase and sale of all Gilead-branded medicines by Safe Chain from January 2020 to the present.

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This letter is without prejudice to any rights and remedies of Gilead, all of which are expressly reserved.

Very truly yours,

Baker & Hostetler LLP

*/s/ Robertson D. Beckerlegge*

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## APPENDIX

### (1) Summary of Incidents in Which Safe Chain Sold Counterfeit Gilead Medicine

#### *New Incidents*

**Sale of Counterfeit BIKTARVY® (Lot CCZCBA):** On Feb. 16, 2021, Gilead was notified by Elm Drugs (New York, New York) that it had dispensed one bottle of BIKTARVY Lot CCZCBA to a patient that was returned because it contained foreign tablets. Elm Drugs provided Gilead an invoice showing that it purchased the bottle from Safe Chain on or about Oct. 9, 2020. Based on photographs of the bottle it appears to have been tampered with.

**Sale of Counterfeit DESCOVY® (Lot # 019815):** On Mar. 2, 2021, Gilead was notified by a patient that their bottle of DESCOVY Lot # 019815 contained VIREAD® tablets and not DESCOVY and that the dispensing pharmacy was Capitol Hill Pharmacy (Washington, D.C.). Capitol Hill Pharmacy provided Gilead a Packing List showing that it ordered the bottle from Safe Chain on February 25, 2021.

#### *Incidents Previously Reported to Safe Chain*

**Sale of Counterfeit BIKTARVY® Lot CCXKVA:** In August 2020, Gilead was notified by White Cross Pharmacy that a patient had returned one bottle of BIKTARVY Lot CCXKVA that contained foreign tablets. White Cross provided Gilead an invoice showing that the bottle had been purchased from Safe Chain. Physical examination of the bottle confirmed that it was tampered with.

On Nov. 23, 2020, Gilead contacted Safe Chain asking it to verify the invoice and asking Safe Chain for its source of this bottle. On Dec. 7, 2020, Safe Chain responded that the invoice was correct, but questioned whether the Lot CCXKVA bottle is the same bottle referenced on the invoice. Further, Safe Chain refused to provide its source of the bottle, claiming only to be “purchasing from an authorized trading partner.” On Dec. 10, 2020, Gilead replied again asking for source information. After numerous assurances by Safe Chain in December that a response was forthcoming, and after Gilead had again requested a response on Jan. 4 and Feb. 17, Safe Chain finally responded on Feb. 22. That response included a “DSCSA TRACEABILITY REPORT” apparently created by Gentek LLC showing that 34 separate BIKTARVY lots totaling 272 bottles, including five bottles of Lot CCXKVA, had been sold in July 2020 by Gilead to Drogueria Betances (Betances) to Gentek to Safe Chain. **Although Betances is a Gilead-authorized distributor, Lot CCXKVA was never sold to it, thus this Traceability Report is falsified and illegitimate.**

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On Feb. 2, 2021, a California Board of Pharmacy investigator asked Gilead to verify the legitimacy of a DSCSA Document that the investigator stated was received from Safe Chain. That document showed that White Cross had purchased two bottles of BIKTARVY Lot CCXKVA, four bottles of BIKTARVY Lot CCXKPA, and two bottles of BIKTARVY Lot CCXKNA from Safe Chain, which had purchased the same bottles from Gentek LLC, which had purchased the bottles from Betances. That document contained information inconsistent with Gilead's records and, therefore, we informed the BoP investigator that the document was falsified and illegitimate.

The information in the Traceability Report Safe Chain provided to Gilead related to this transaction is inconsistent with the DSCSA Document Safe Chain provided to the California BoP. The Traceability Report indicates that five bottles of Lot CCXKVA were purchased from Gentek while the DSCSA Document shows only two bottles of Lot CCXKVA were purchased from Gentek.

**Sale of Counterfeit BIKTARVY Lot CCZCFA:** On Feb. 12, 2021, Safe Chain contacted Gilead to notify it that one BIKTARVY Lot CCZCFA bottle had been returned to Safe Chain by Medicine Shoppe Pharmacy # 1802 (Silver Spring, Maryland). Gilead contacted the pharmacy and subsequently learned that a patient notified the pharmacy on Feb. 3 that the bottle contained foreign tablets. Gilead has received the bottle and is in the process of analyzing it. **The bottle appears to be tampered with.**

Gilead responded to Safe Chain on Feb. 17 seeking source information for Lot CCZCFA and any and all communications between Safe Chain and Gentek regarding this Lot. Safe Chain claimed that Gentek instructed Safe Chain to destroy the bottle as it was a "mixed batch error from the Gilead Authorized Distributor." On Feb. 22, Safe Chain provided Gilead with DSCSA Documents and DSCSA Traceability Reports. One DSCSA Document (Doc# 00000019202) shows that one bottle of Lot CCZCFA was sold by Gilead to Betances (on 10/5/20) to Gentek (on 10/6/20) to Safe Chain (on 1/7/21) to Medicine Shoppe (on 1/8/21). A DSCSA Traceability Report (Invoice 2678) shows that in July 2020, three bottles of Lot CCZCFA were sold by Gilead to Betances to Gentek to Safe Chain. And another DSCSA Traceability Report (Invoice 2736) indicates that two bottles of Lot CCZCFA were sold by Gilead to Betances (on 10/21/20) to Gentek (on 10/26/20) to Safe Chain (on 10/27/20). None of these DSCSA Documents or Traceability Reports are consistent with each other either in terms of the number of bottles of Lot CCZCFA sold or the dates on which they were sold. Further, we have confirmed with Betances that it never sold this Lot to Gentek. **This documentation appears to be falsified and illegitimate.**



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Safe Chain ignored Gilead's request for any and all communication with or contact information for Gentek.

**Sale of Counterfeit BIKTARVY Lot CDFYCA:** During the course of investigating Safe Chain's sale of counterfeit BIKTARVY Lot CCZCFA to Medicine Shoppe, Gilead learned of another situation in which Medicine Shoppe # 1802 purchased from Safe Chain a bottle of BIKTARVY that was returned by a patient. Medicine Shoppe informed Gilead that in October 2020, a Medicine Shoppe patient returned a bottle of BIKTARVY Lot CDFYCA as the bottle contained Seroquel tablets instead of BIKTARVY. The pharmacy stated it reported the matter to Safe Chain and heard nothing further.

Gilead brought this to Safe Chain's attention on Feb. 18. and followed up again the morning of Feb. 22 seeking additional information about the sale. Later, on Feb. 22, Safe Chain responded by attaching documents purportedly related to Safe Chain's purchase of Lot CDFYCA from Gentek. Further, regarding the patient's return of Lot CDFYCA, Safe Chain claimed, without any supporting documents or details about the communication, that it "reported this to you but never heard anything back" and that "Safe Chain initiated an investigation by notifying Gilead and seeking direction. We never heard back from Gilead." Gilead immediately asked Safe Chain to substantiate these statements as Gilead has no record of receiving this notification from Safe Chain. Gilead has yet to receive a response to its request.

Regarding Safe Chain's source of Lot CDFYCA, on Feb. 22 Safe Chain provided Gilead a copy of a DSCSA Traceability Report (Invoice 2736) showing that four bottles of Lot CDFYCA were sold by Gilead to Betances (on 10/21/20) to Gentek (on 10/26/20) to Safe Chain (on 10/27/20). Given that the DSCSA Traceability Report indicates Safe Chain purchased the bottle from Gentek on Oct. 27 and Medicine Shoppe stated the patient returned the bottle in October 2020, it is likely this documentation does not correlate to the bottle of Lot CDFYCA that Medicine Shoppe sold and that was returned. Further, we have confirmed with Betances that it never sold this Lot to Gentek. **This documentation appears to be falsified and illegitimate.**

**(2) Requests to Verify DSCSA Documentation That Resulted in the Identification of Falsified and Illegitimate DSCSA Transaction History Documentation Involving Safe Chain**

**Request to Verify DSCSA Documentation regarding BIKTARVY Lot CDGXKA:** On Oct. 5, 2020, Safe Chain asked Gilead to verify a DSCSA Document that purported to show that Gilead sold five bottles of BIKTARVY Lot CDGXKA to Rochester Drug Co-Op Inc. Gilead determined that the information contained in the document did not match Gilead's records and

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thus the document was falsified and illegitimate. On Oct. 9, Gilead responded that the information contained within the document was “inconsistent with our records,” asked that Safe Chain quarantine any product associated with this document that remains in Safe Chain’s possession, that Safe Chain report this matter to the FDA, and that Safe Chain update Gilead on the steps it had taken. Gilead heard nothing back on the matter.

On Nov. 23, Gilead sent a letter to Safe Chain requesting an update on this matter. On Dec. 7, Safe Chain responded by mis-stating the facts and claiming that Gilead had not replied to it until Nov. 9, but that Safe Chain had quarantined multiple BIKTARVY bottles from this Lot, that it was Gilead’s responsibility to notify the FDA and asked us for further information. On Dec. 10, Gilead replied that it was not Gilead’s legal responsibility to notify the FDA about this instance of fraudulent documentation, but that we were happy to should Safe Chain prefer not to. Despite assurances on Dec. 10 and Dec. 18 from Safe Chain that it would respond, and Gilead following up on Jan. 4, 2021 and Feb. 17, we have heard nothing further on this matter.

**Request to Verify DSCSA Documentation regarding multiple GENVOYA®, DESCOVY and BIKTARVY Lots:**

On Jan. 29, 2021, Gilead was asked by a downstream purchaser to verify multiple invoices and DSCSA Documents relating to 41 bottles of GENVOYA, DESCOVY and BIKTARVY that it had purchased from Safe Chain. The documentation indicated that Safe Chain had purchased all bottles from Gentek which had purchased the bottles from Betances. As stated, Gilead has confirmed with Betances that it has never sold Gilead-branded product to Gentek, therefore these documents are falsified and illegitimate.